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Efficacy of Shortwave Diathermy in Managing Discogenic Low Back Pain in Adults Protocol for a Two Arm Randomized Controlled Trial

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Abstract: Background: The additional benefit of shortwave diathermy alongside conventional physiotherapy remains uncertain for adults with discogenic low back pain. Previous studies have used heterogeneous treatment parameters and have methodological limitations. This ongoing trial evaluates the additional benefit of active shortwave diathermy compared with sham treatment when both groups receive the same conventional physiotherapy programme and home exercise advice. Methods: This is a two-centre, two-arm, parallel-group randomised controlled trial of adults aged 20–60 years with clinically diagnosed discogenic low back pain in Sirajganj, Bangladesh. Recruitment and randomisation took place from 1 June to 27 July 2026, and follow-up is ongoing. A total of 208 participants were recruited and randomised, with 104 allocated to active shortwave diathermy and 104 to sham treatment using a sex-stratified, computer-generated sequence and concealed allocation. The protocol specifies twelve sessions over four weeks. Active treatment uses a carrier frequency of 27.12 MHz for 20 minutes per session; the sham procedure delivers no therapeutic shortwave energy. Both groups receive the same conventional physiotherapy and home exercise advice. Assessments are scheduled at baseline and weeks 4, 12 and 24 after randomisation. The primary endpoint is pain intensity on a 10-cm visual analogue scale at week 4. Disability and safety are secondary outcomes; lumbar range of motion, psychological measures and satisfaction are exploratory outcomes. The design specifies blinded outcome assessors. Analyses will follow the intention-to-treat principle and report between-group estimates with 95% confidence intervals. No outcome results are reported in this protocol manuscript. Discussion: The trial will estimate the additional benefit and harms of active SWD within a shared rehabilitation programme, rather than the effectiveness of SWD used alone. Interpretation will account for diagnostic uncertainty, possible participant unblinding, adherence to supervised and home exercises, and additional care.

Keywords: rehabilitation, deep heating, sham treatment, functional disability, pain assessment, randomised controlled trial

INTRODUCTION

Discogenic low back pain is attributed to the intervertebral disc and can limit mobility and everyday activity. It should not be treated as interchangeable with disc herniation, radiculopathy or all nonspecific low back pain. Establishing the disc as the pain source is difficult because clinical presentations overlap and a universally accepted diagnostic standard is lacking [1]. A trial in this population therefore requires a documented clinical assessment and exclusion of alternative causes rather than reliance on a diagnostic label alone.

Nonpharmacological management, including exercise and rehabilitation, is recommended for chronic low back pain [2]. These recommendations support an active rehabilitation comparator, although evidence from broad low back pain populations does not establish the effectiveness of every additional modality in a clinically defined discogenic population. Shortwave diathermy (SWD) applies electromagnetic energy in continuous or pulsed modes. Its physiological effects and safety depend on the delivered dose and application technique [3].

A systematic review of SWD for chronic low back pain identified five studies involving 731 participants and highlighted weak methodology and inconsistent prescription parameters [4]. A subsequent review of electromagnetic diathermy across musculoskeletal disorders also found uncertainty and heterogeneity in the evidence [5]. Findings across different conditions and technologies cannot be transferred directly to discogenic low back pain. A randomised study of patients with lumbar disc herniation examined ultrasound and SWD within physiotherapy programmes [6], but that population and treatment comparison differ from the present trial.

The trial compares active with sham SWD while specifying the same conventional physiotherapy and home exercise advice in both groups. This design estimates the incremental effect of adding therapeutic shortwave energy to a shared rehabilitation programme. Assessment after treatment and at later follow-up distinguishes the immediate endpoint from persistence of any benefit. Adherence and adverse-event records will place observed improvement in its clinical context.

Objectives and Hypothesis

The primary objective is to estimate the additional effect of active SWD, compared with sham SWD, on week-4 VAS pain intensity when both groups receive the same conventional physiotherapy and home exercise advice. The between-group difference will be adjusted for baseline pain. Secondary objectives are to evaluate functional disability, longer-term pain and disability, and treatment-related adverse events. Lumbar range of motion, perceived stress, psychological distress and treatment satisfaction will be evaluated as exploratory outcomes. The trial does not evaluate SWD as a stand-alone treatment.

The primary null hypothesis is that the adjusted mean VAS pain score at week 4 does not differ between active and sham SWD when both groups receive the same conventional physiotherapy and home exercise advice. The alternative hypothesis is that the groups differ, with lower pain scores anticipated in the active group. A two-sided test will be used; benefit will not be assumed before analysis.

METHODS AND ANALYSIS

Recruitment has ended and follow-up is ongoing. The methods below describe the trial design and procedures implemented, as confirmed by the investigator. No comparative outcome results are reported here. The continuous-outcome sample-size sensitivity calculation in this manuscript revision is distinguished from the proportions-based calculation in the earlier proposal. It is not presented as the original pre-recruitment

calculation. Any protocol amendments or deviations will be reported with their dates and reasons in the final trial report.

Trial Design and Reporting

This is a two-centre, two-arm, parallel-group superiority randomised controlled trial with a 1:1 allocation ratio. The protocol specifies four weeks of treatment, followed by assessments at weeks 12 and 24 after randomisation. The manuscript is organised with reference to SPIRIT 2025 [7], and the completed trial will be reported using CONSORT 2025 [8]. The schedule of enrolment, interventions and assessments is provided in Table 1; the treatment comparison is summarised in Table 2. Figure 1 presents the trial pathway and confirmed randomised allocation; outcome and analysis counts are not reported in this protocol manuscript.

Recruitment and randomisation took place from 1 June to 27 July 2026, and 208 participants were recruited. Ethics approval was obtained before recruitment. Participant follow-up is ongoing, with the final scheduled 24-week assessment on 11 January 2027. The work plan and assessment windows are provided in section 2.17.

Setting and Study Organisation

The participating sites are Akhter Community Based Rehabilitation Centre and Physio Pulse Advance Physiotherapy Centre in Sirajganj District, Bangladesh. Both centres provide physiotherapy services to adults from urban and rural communities. The protocol assigns treatment delivery to qualified physiotherapists using the same written procedures. The coordinating principal investigator is responsible for recruitment oversight, training, treatment documentation, safety and data management across sites.

The trial procedures specify training in eligibility screening, consent, allocation concealment, intervention delivery and outcome measurement. Site records and the treatment manual document equipment, quality checks and treatment delivery. Referral arrangements support clinical evaluation when required.

Participants and Eligibility

Adults of either sex aged 20–60 years were eligible if they have clinically diagnosed discogenic low back pain, symptoms for at least four weeks, a screening Numeric Pain Rating Scale score of at least 3/10, the ability to understand study instructions and complete assessments, and the ability to attend treatment. The protocol requires written informed consent before study procedures. The numeric scale is used only for screening; the VAS will be used for the primary outcome. Because the minimum duration is four weeks, the enrolled population is not described as exclusively chronic.

Under the operational screening rule, an experienced physiotherapist classifies the presentation as clinically suspected discogenic low back pain when all of the following apply: predominantly axial lumbar pain; reproducible aggravation of familiar pain with sitting, forward bending or lifting; and no clinical findings identifying a more likely alternative pain source or an exclusion condition. History records symptom duration, dominant pain location,

aggravating and relieving factors and leg symptoms. Examination includes lower-limb motor, sensory and reflex screening and neurodynamic tests when indicated. Centralisation with repeated movement may support the assessment but is not mandatory. The clinician documents the supporting findings and differential diagnosis. Uncertain cases are reviewed by a second experienced clinician before allocation. This is a study-specific clinical classification, not a validated diagnostic test or confirmation that a disc is the sole pain source [1].

Existing imaging is reviewed when available and relevant, but imaging is not ordered solely to establish trial eligibility. Imaging requested for clinical red flags follows usual referral care. Disc degeneration on imaging alone does not establish a discogenic diagnosis, and provocative discography is not performed solely for this study. Clinically suspected cases are described as such in reporting, and diagnostic uncertainty is retained as a limitation [1].

Exclusion criteria include progressive neurological weakness; new bowel or bladder dysfunction; saddle anaesthesia or suspected cauda equina syndrome; suspected fracture, infection, malignancy or inflammatory spinal disease; recent spinal surgery; severe uncontrolled medical illness; contraindications to SWD, including implanted electronic devices; pregnancy where SWD is contraindicated; significant sensory impairment affecting heat detection; participation in another intervention trial; or inability to complete outcome measures. For the screening rule, recent spinal surgery means surgery within the preceding six months. This is a study eligibility convention, not an assertion that every person is safe for SWD or exercise after six months; prior surgery, implants and current clinical restrictions are reviewed individually. Participants with red flags are referred for appropriate clinical evaluation.

Recruitment and Consent

Patients attending the participating centres were screened for eligibility. The protocol specifies consecutive screening and a log of eligibility and reasons for non-enrolment without unnecessary identifiers. Study information is explained in a language the patient understands, with an opportunity to ask questions and consider participation. Consent and baseline assessment precede randomisation. Participation is voluntary, and declining or withdrawing does not affect usual care.

Sample Size

The protocol recruitment target was 208 participants, with intended 1:1 allocation and 104 per group. A total of 208 participants were recruited and randomised, with 104 allocated to each group. The earlier proposal used a proportions-based calculation. The continuous-outcome calculation presented in this manuscript revision evaluates the sensitivity of that target for the primary week-4 VAS endpoint; it is not described as the calculation that originally determined recruitment. The assumed group difference is 1.5 cm on the 0–10 cm VAS, with a common outcome standard deviation of 3.0 cm, giving a standardised difference of 0.50. The target difference is a proposed group-level effect, not an established minimum important change for an individual. DELTA2 principles inform the interpretation of these assumptions [9].

A related Bangladesh SWD protocol assumed an SD of 3.0 on a 0–10 numerical pain scale [10]. That assumption is an external benchmark only: numerical ratings and VAS are not interchangeable, and neither the SD nor the 1.5-cm difference is a locally validated estimate for this discogenic population. The SD is treated as a conservative working assumption for the sensitivity calculation. No claim is made that patient consultation or local pilot VAS data established these assumptions before recruitment. The continuous-outcome assumptions reported here belong to the present sensitivity calculation and are distinguished from the original proportions-based justification.

For a two-sided independent-groups t test at alpha = 0.05, a difference of 1.5 cm and SD of 3.0 cm require 64 analysable participants per group for 80% power, using the noncentral t distribution. Allowing 20% missing primary outcomes requires 80 recruits per group (64/0.80), or 160 in total. The recruitment target of 208 exceeds this requirement. With conservatively rounded retained group sizes of 104, 93 and 83, power for the selected difference is 94.8%, 92.4% and 89.3%, respectively (Table 3). The calculation assumes no gain from baseline adjustment. Smaller-effect sensitivity scenarios are also reported; a smaller clinically important effect or larger SD may require a larger sample. The recruitment target of 208 was achieved, with 104 participants randomised to each group. Outcome completeness, losses and analysis denominators will be reported from the trial records in the completed trial report; the power scenarios in Table 3 remain hypothetical.

Randomisation and Allocation Concealment

An independent person who is not involved in recruitment, treatment or outcome assessment generated the randomisation sequence by computer, stratified by sex, with allocation in a 1:1 ratio. Sex stratification is intended to balance treatment assignment within strata; it does not guarantee that the final sample will include exactly 52 men and 52 women in each group. The sequence-generation procedure and allocation implementation are documented separately from recruitment records.

Assignments were placed in sequentially numbered, opaque, sealed envelopes corresponding to the relevant stratum. Following consent and completion of baseline assessment, the next envelope was opened to assign treatment. The envelope number, opening date and responsible staff member are recorded. Recruiters and assessors do not have access to the allocation sequence. Allocation is not changed in response to participant characteristics or preferences.

Blinding

Outcome assessors remain unaware of treatment allocation. Participants receive an active or sham procedure with equivalent positioning, session duration and therapist contact to support participant blinding. Treating physiotherapists cannot be blinded because they must configure and monitor the device. Participants and therapists are asked not to disclose allocation during outcome assessment. Treatment records are kept separate from assessor records.

Warmth during active SWD may reveal allocation. The trial is therefore described as assessor-blinded, with attempted participant blinding. At week 4, after outcome

assessment, participants were asked whether they believed they had received active SWD, sham SWD or did not know, and the reason for their response was recorded. These responses will be summarised by allocated group in the trial report. Successful participant blinding is not assumed; accidental assessor unblinding is documented when identified.

Active Shortwave Diathermy

The protocol-specified active treatment is continuous shortwave diathermy at 27.12 MHz for 20 minutes per session, three sessions weekly for four weeks (12 sessions). This mode and duration have precedents in low-back-pain studies [6,10]; they are a selected research regimen, not a universally recommended dose. The protocol allows approximately 40 minutes per combined visit, including the common physiotherapy programme. A trained physiotherapist will screen contraindications and skin sensation before each treatment. Intensity will be increased gradually from the lowest setting to mild, comfortable warmth, within the manufacturer's permitted limits, with repeated comfort checks. Excessive heat, new symptoms or a safety concern will require immediate cessation.

The protocol specifies the BTL-6000 Shortwave 400 (BTL Industries Ltd., United Kingdom) [11]. This model supports capacitive and inductive application; the selected trial method remains capacitive continuous SWD at 27.12 MHz. The manufacturer specifies maximum output of 200 W continuous and 400 W pulsed [11]; these are equipment limits, not the prescribed participant dose. Intensity will be titrated to mild, comfortable warmth without exceeding the connected applicator's permitted limit. Two matched circular capacitive applicators of 85 mm diameter, secured on the device support arms, will be placed coplanarly on either side of the lumbar region, with the participant prone when tolerated. For the selected 85-mm capacitive applicator, the manufacturer specifies a maximum of 150 W in continuous mode and 300 W in pulsed mode [11]. This trial will use continuous mode, with output titrated to mild, comfortable warmth and never exceeding 150 W; 150 W is the accessory limit, not a fixed treatment dose. Both centres will use the same verified accessory and dry insulation. Each applicator face will be positioned parallel to the treated skin with a 3.0-cm electrode-to-skin gap, measured perpendicular to the skin and maintained throughout the session. This is the investigator-selected trial setting; compatibility with the installed 85-mm applicators and manufacturer instructions was included in the equipment verification procedure. The 3.0-cm gap will be maintained between each applicator face and the skin. The two applicators will be positioned on either side of the lumbar region according to the manufacturer's instructions and the treatment placement guide. The shortest edge-to-edge distance between the two applicators, and both applicator-to-skin gaps, will be measured in centimetres and recorded at each session. The same positioning procedure will be used in the active and sham groups. Equipment, accessories, service status and electrical safety are subject to technician verification before use. Each session log will record output setting, applicator, placement, actual spacing, duration, skin checks, warmth and deviations.

Sham Procedure and Common Physiotherapy

The protocol-specified sham procedure uses the same BTL-6000 Shortwave 400 casing, electrode arrangement, positioning, 20-minute duration and therapist contact, with its rear

main power switch in the off position and the shortwave unit switched off and disconnected from its electrical power source throughout the session. This selects an off-device sham rather than an unverified internal zero-output mode; no therapeutic shortwave energy will be generated and no additional heater will be used. A separate timer will be used. Before every sham session, the therapist will document the off state, power disconnection and absence of any independent power source. The sham configuration is subject to technician verification to confirm that it cannot generate energy. No modification of internal wiring is permitted. The device display and power connection will be concealed from participants and outcome assessors in both groups. The neutral explanation will be that treatment sensations can vary. Warmth may reveal active allocation, so assessor blinding remains important; participant allocation guesses were collected at week 4 as described in section 2.7. The equipment checklist forms part of the treatment documentation.

Both groups received the same conventional physiotherapy: education, posture and activity advice, gentle lumbar mobility exercises, core-stabilisation exercises, hip and hamstring flexibility exercises, and functional activity training, with the same home exercise instructions. Programme content, starting doses, progression rules, supervised contact time and home exercise guidance were standardised across groups, with individual symptom-related modifications documented. The exercise schedule and progression rules are provided in Appendix A. Session logs document exercise selection, delivered dose, progression and modifications. This shared rehabilitation programme defines the background care against which the additional effect of active versus sham SWD is evaluated.

Session attendance, intervention settings, exercise delivery and modifications will be recorded in structured logs. Home exercise completion and additional care will be recorded at follow-up. Participants will not be denied clinically necessary medication or treatment. During the four-week intervention, they will be asked not to start additional elective physiotherapy or electrotherapy for the same condition. Clinically necessary rescue care is permitted and will be documented, including its indication, date, type and medication dose where applicable. Additional care will not trigger exclusion from the intention-to-treat analysis.

Outcomes and Measurement

Assessments are scheduled before randomisation and at weeks 4, 12 and 24 after randomisation. The primary endpoint is VAS pain intensity at week 4. Participants mark a 10-cm horizontal line anchored by no pain and worst pain imaginable, indicating their current low back pain at the assessment. Distance from the no-pain anchor is measured in centimetres to one decimal place and recorded from 0 to 10; higher scores indicate more pain [12]. The same instructions and assessment order are used at every visit. The outcome assessor completes measurements before discussing adherence or additional treatment, reducing the chance of disclosure of allocation.

Functional disability is measured with the Oswestry Disability Index (ODI). Its ten sections are scored from 0 to 5; the observed total is divided by the maximum possible total for completed sections and multiplied by 100. Scores range from 0% to 100%, with higher scores indicating greater disability [13]. Instrument use and permission status are reported below; incomplete questionnaire scoring follows the stated scoring rules. ODI at week 4 is

the key secondary endpoint, with VAS and ODI at weeks 12 and 24 providing longer-term outcomes.

Exploratory outcomes are regional trunk range of motion, perceived stress using the Bangla PSS-10, and anxiety/depression symptoms using the Bangla PHQ-4. The author-endorsed Bangla PSS-10 evaluated in Bangladesh was used: scores range from 0 to 40 after reversing items 4, 5, 7 and 8; the recall period is the preceding month [14]. The PHQ-4 total ranges from 0 to 12 and uses a two-week recall period [15]; the Bangla version evaluated by Mozumder and colleagues is selected [16]. Both have community validation evidence, which does not establish responsiveness or diagnostic accuracy in this particular trial population. Scores will be analysed as exploratory outcomes without psychiatric diagnoses. Mobility, PSS-10 and PHQ-4 were collected at baseline and week 4, with further assessments scheduled at weeks 12 and 24.

For flexion and extension, the participant stands upright with knees extended. The iliac crest provides the lateral reference, with the movable arm aligned to the axillary line; the neutral alignment is recorded before slow movement to a comfortable endpoint. Arms are held forward for flexion and behind the neck for extension when tolerable. This procedure is adapted from published trunk goniometry [17].

For lateral bending, the goniometer axis is placed over S1, the stationary arm vertical and the movable arm aligned towards the C7 spinous process. The participant bends slowly to each side without deliberate rotation, following a published regional measurement approach [18]. Three tolerable repetitions per direction are averaged, using the same examiner where possible. Pain-limited or unobtainable measurements are recorded with their reason. These are regional trunk angles, not isolated lumbar-segment motion; landmark placement and compensatory movement may affect precision.

Satisfaction was assessed at week 4 with a single exploratory item: "Overall, how satisfied are you with the treatment you received?" Response options were very dissatisfied, dissatisfied, neither satisfied nor dissatisfied, satisfied or very satisfied, coded 1-5. This study-specific item is not claimed to be a validated questionnaire. It will be analysed as an ordered categorical outcome and will not replace pain or disability as an efficacy endpoint.

Baseline information included age, sex, education, occupation, symptom history, comorbidity, medication and previous physiotherapy. Height and weight were measured using calibrated equipment, and body mass index was calculated as weight in kilograms divided by squared height in metres. Blood pressure were measured after rest using a digital monitor. These variables characterise the sample rather than replace the prespecified trial outcomes.

Measurement procedures and the stated instruments were used in the study, as confirmed by the investigator. Data collection uses Bangla instructions and a standardised case-report form. Neutral reading assistance is provided when needed without changing response options or scoring. No additional claim is made that the study conducted a new forward/back-translation programme, a separate psychometric validation or the previously proposed approximately 10-person cognitive-pretesting procedure. The preparatory periods in the work plan are scheduling information and do not establish completion of those procedures.

Disability was measured using the ODI version 2.1a, with all ten domains retained. The Bangla PSS-10 and Bangla PHQ-4 were used with their stated recall periods and scoring. Published Bangla validation evidence does not establish responsiveness or diagnostic accuracy in this trial population. This investigator-initiated, self-funded PhD study received ethical approval from the Ethical Committee of the School of Science and Technology, Bangladesh Open University, on 24 April 2026 (reference: PhD/BOU/22-23/26/1162). The ODI and PSS-10 were used as outcome measures for academic research. No study-specific instrument licences were obtained. This status is disclosed transparently, and the manuscript does not reproduce the full questionnaires. Ethical approval and instrument-use authorisation are recognised as separate requirements. The official ODI conditions specify a licence agreement, and the PSS owner directs permission requests through Mapi/ePROVIDE [19,20]; no authorisation is claimed for the study's use of these instruments. The original PHQ-4 notice permits reproduction, translation, display and distribution without separate permission [21]; that notice does not establish the reuse conditions of every independently prepared translation.

Safety and Retention

Adverse events will be recorded during every treatment session and at follow-up, including excessive warmth, skin injury, symptom exacerbation and events requiring medical assessment. The log will record onset, severity, duration, action taken, outcome and the clinician's assessment of relation to treatment. Serious or unexpected events will be escalated to the principal investigator and reported according to the ethics committee and applicable institutional requirements. Emergency referral arrangements will be confirmed at both sites.

Treatment may stop for a contraindication, adverse event, participant request or clinician concern; consented follow-up will continue. Urgent events will receive immediate clinical assessment and emergency referral. An independent registered physician with rehabilitation or musculoskeletal-care experience, who neither delivers trial treatment nor assesses efficacy outcomes, will review serious or unexpected events. The safety procedures assign independent review to a physician whose qualifications, conflicts and contact details are documented in the safety roster. Serious events will reach the PI and reviewer within 24 hours of awareness. The proposed committee-notification plan is an initial report within 24 hours for a serious or unexpected potentially treatment-related event, followed by a detailed report within seven calendar days and updates until resolution. Any shorter or different committee or regulatory requirement takes precedence; these are proposed operational targets, not assertions of a Bangladesh statutory deadline [22]. A potentially related serious event triggers independent review and committee advice; any further recruitment is suspended pending that review. Referral and necessary care will not wait for causality adjudication. Under the proposed injury-care plan, the principal investigator, Md. Akhter Hossain, will arrange and pay for medically necessary assessment and treatment of research-related injury from the study's personal funding. This responsibility forms part of the injury-care arrangements and is subject to institutional requirements. Appropriate compensation will be addressed separately under the applicable institutional, ethics and legal requirements [23]. The compensation mechanism, responsible payer and funding are

governed by the approved participant information and applicable institutional and ethics requirements. Consent will not require participants to waive their applicable rights.

Data Management

Each participant will be assigned a study code. Identifiers and contact details will be stored separately from analysis data; paper records will be locked and electronic records protected by role-based access and secure backups. The principal investigator will be the data custodian. Data entry will include independent verification of primary VAS and ODI values, range checks, duplicate-record checks and consistency checks against visit dates and source forms. Queries and corrections will be dated and logged; plausible extreme values will be retained, and only verified transcription errors will be corrected. The final database will be locked after documented query resolution, before comparative outcome analysis. The proposed trial retention period is at least ten years after trial completion or the final study publication, whichever is later; any longer institutional, committee or legal requirement will take precedence. This is a selected study policy, not a universal international requirement. The PI will retain the signed consent forms, source records, treatment and safety logs, analysis data, syntax and audit trail securely, with restricted access and backed-up electronic copies. At the end of the authorised retention period, paper records will be securely destroyed and electronic identifiers irreversibly deleted, subject to any continuing audit or legal hold.

Statistical Analysis

Analyses will follow the intention-to-treat principle, retaining participants in their randomised groups irrespective of treatment adherence. The main estimand is the difference in mean week-4 VAS scores between assignment to active SWD and assignment to sham SWD, with the same conventional physiotherapy and home exercise advice specified in both groups. This estimates the additional effect of assigning active SWD within the shared rehabilitation programme, not the effect of SWD used alone. Follow-up outcomes will be sought after treatment discontinuation where consent allows. Baseline characteristics will be summarised descriptively without significance tests for randomisation balance.

The primary comparison will use analysis of covariance with week-4 VAS as the outcome and treatment group, baseline VAS, sex and study centre as predictors. The active-minus-sham adjusted mean difference, 95% confidence interval and two-sided P value will be reported; negative differences favour active treatment. The primary significance level will be 0.05. Sex and centre will be retained regardless of their statistical significance. Model fit, linearity and residual behaviour will be examined. The baseline-outcome relationship will be linear in the primary model; no outcome-driven covariate selection or participant exclusion will be performed. A supplementary participant-level bootstrap analysis with 5,000 resamples within treatment groups will assess the robustness of the complete-case estimate to distributional assumptions.

Week-4 ODI will be analysed by the same adjusted comparison using baseline ODI instead of baseline VAS. Separate linear mixed models for VAS and ODI will examine outcomes at weeks 4, 12 and 24, with treatment, categorical time, treatment-by-time

interaction, baseline outcome, sex and centre as fixed effects. Within-participant correlation will be represented by an unstructured residual covariance over the three visits, without a redundant random intercept. Models will use restricted maximum likelihood. If the unstructured model does not converge, compound-symmetric covariance will be used and the change documented.

Baseline-adjusted group differences at each visit will be reported with 95% confidence intervals. Week-4 pain is the sole confirmatory endpoint; ODI and later pain estimates will be interpreted as secondary. Mobility, PSS-10 and PHQ-4 will be examined descriptively and with analogous models where appropriate. Satisfaction responses will be reported by category; an exploratory proportional-odds model may be used if its assumptions and category counts permit. Secondary and exploratory comparisons will not be used to claim multiple independent confirmatory effects.

The primary intention-to-treat analysis will use multiple imputation if primary outcome values are missing, under a missing-at-random assumption conditional on observed information. Fifty imputed datasets will be generated by chained equations. The imputation model will include treatment, sex, centre, age, symptom duration, baseline outcomes and available follow-up VAS and ODI measurements; treatment-by-time terms will be represented consistently with repeated-outcome analyses. For SPSS 25, fully conditional specification will use linear models for scale variables and logistic models for categorical variables, with prespecified valid ranges (VAS 0-10; ODI 0-100) and imputation diagnostics. Predictive mean matching will not be assumed to be available in this version. The statistician will verify model fit, bounds and convergence before pooling; any necessary supplementary implementation will be specified in the analysis plan. Estimates will be combined using Rubin's rules. If all primary outcomes are observed, imputation is unnecessary. Missingness, reasons for missing visits and analysis denominators will be reported by treatment group. Identifiers will never enter the imputation model.

Sensitivity analyses will include complete-case ANCOVA and pattern-mixture scenarios for missing week-4 VAS values. In the latter, imputed VAS values in the active group will be shifted upwards by 0.5 and 1.0 points, leaving observed values and control-group imputations unchanged; reverse scenarios will apply the same shifts to the control group. Shifted scores will remain within 0-10. These prespecified stress-test values are analytical scenarios, not asserted clinical thresholds. A supplementary per-protocol analysis will include participants attending at least 10 of 12 planned sessions without a major intervention error, while retaining their assigned group. It will be interpreted cautiously because adherence is not randomised. Last observation carried forward will not be used.

Adherence will be summarised as sessions attended out of 12 and reported home exercise completion. Adverse events will be reported by treatment received alongside randomised-group safety summaries, with denominators stated. Analyses will use IBM SPSS Statistics version 25. The statistician will confirm access to the required Missing Values and Advanced Statistics modules before database lock. Saved syntax and the dated analysis plan will specify imputation constraints, covariance structures and pooling.

If an analysis is unavailable in the installed modules, a validated supplementary implementation and its software version will be documented before reviewing treatment comparisons. Deviations will be reported with reasons.

Intervention Standardisation and Monitoring

The protocol requires treating physiotherapists to be trained in the common manual before recruitment, including treatment documentation and assessment procedures. Training content and dates are documented in site records. Therapists will complete a checklist at every session. The coordinating principal investigator will review recruitment, adherence, deviations and safety logs monthly at both centres. Primary outcomes will undergo complete source verification; a random 10% of other case-report forms will be checked each month. Identified errors will trigger documented correction and targeted retraining. The independent safety reviewer will receive serious-event reports and a monthly summary. Material safety concerns may trigger temporary suspension pending clinical and ethics review.

Ethics and Dissemination

Ethics approval has been obtained from the Ethical Committee of the School of Science and Technology, Bangladesh Open University (BOU), approval reference PhD/BOU/22-23/26/1162, dated 24 April 2026. Recruitment and randomisation took place from 1 June to 27 July 2026. Written informed consent is required before baseline assessment and randomisation. Participants may decline or withdraw without affecting usual care. Findings will be disseminated through peer-reviewed publication and professional presentations irrespective of the direction of the results. A plain-language summary will be prepared for participants.

Patient and Public Involvement

No patients or members of the public were involved in developing the initial protocol. No completed pre-recruitment advisory-group activity is reported. Any involvement during follow-up or dissemination will be described separately with its timing. Participants will be offered a plain-language summary after study completion.

Trial Status and Timeline

Recruitment and randomisation took place from 1 June to 27 July 2026, and 208 participants were recruited and randomised, with 104 allocated to each group. Ethics approval was issued on 24 April 2026 by the Ethical Committee of the School of Science and Technology, Bangladesh Open University, reference PhD/BOU/22-23/26/1162. As of 11 October 2026, follow-up is ongoing. The final scheduled 24-week assessment is 11 January 2027. The current manuscript is revision 1.5, dated 11 October 2026. This manuscript revision date is distinct from the ethics approval date; no original approved protocol version number is supplied in the ethics certificate. The editable work plan covers January 2026 to March 2027. Final analysis follows completion of follow-up, resolution of data queries and database lock. The ethics certificate specifies an overall research duration of three years; this work plan schedules the trial activities within that wider research period.

Table 1: Schedule of enrolment interventions and assessments

Activity	2026												2027		
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Literature review	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Title submission	■														
Title selection	■														
Protocol development		■													
Protocol submission and presentation			■												
Ethics application and approval				■											
Pretesting after ethics approval					■										
Preparation for data collection					■										
Recruitment and training of data collectors					■										
Participant recruitment, randomisation and baseline assessment						■	■								
Four-week treatment and week 4 assessment						■	■	■							
Week 12 follow-up assessment								■	■	■					
Week 24 final follow-up assessment											■	■	■		
Data entry and checking						■	■	■	■	■	■	■	■		
Final data checking and database lock													■		
Final data analysis after database lock													■	■	
Report writing														■	■
Final report submission															■

Assessment windows from the first and last randomisation dates: week 4, 29 June to 24 August 2026; week 12, 24 August to 19 October 2026; week 24, 16 November 2026 to 11 January 2027. Each assessment is timed from the individual participant's randomisation date.

Note. Shaded cells indicate scheduled activity periods, not verified completion. Preparatory periods are based on the supplied work plan. Pretesting is scheduled in May 2026, after ethics approval dated 24 April 2026. Recruitment dates are reported in the trial status text. Follow-up windows are calculated from individual randomisation dates; actual attendance and deviations must be documented in study records. Final database lock is scheduled after the last follow-up and resolution of data queries in January 2027, followed by analysis in January–February, report writing in February–March and report submission in March 2027.

DISCUSSION

This trial addresses uncertainty about the additional benefit of SWD within an active rehabilitation programme. Providing the same conventional physiotherapy, home exercise advice and progression rules in both groups helps make the contrast one of active versus sham SWD under comparable background care. Concealed allocation and blinded outcome assessment support the comparison. The interpretation remains specific to adding SWD to this programme; it does not establish the effectiveness of SWD alone. Follow-up beyond the four-week treatment period will allow examination of the durability of any observed pain or disability difference.

A published Bangladesh trial protocol evaluates continuous SWD for chronic nonspecific low back pain [10]. The present trial addresses a clinically classified discogenic population in Sirajganj, with eligibility beginning at four weeks of symptoms and VAS pain as the primary outcome. These differences define the scope of this separate study; they do not establish that SWD is effective or that all participants have confirmed disc pathology.

Several limitations require consideration. Clinical classification cannot establish the intervertebral disc as the pain source with certainty, and diagnostic overlap may affect treatment response. Participants with symptoms of four weeks or longer will include different symptom durations. Findings should therefore be interpreted for the enrolled clinical phenotype and duration distribution, rather than extended automatically to all chronic low back pain or lumbar disc herniation.

Therapists will know the assigned intervention, and warmth during active treatment may compromise participant blinding. Pain, disability and psychological outcomes are self-reported and may be influenced by treatment expectations. Consistent therapist contact and assessor procedures can reduce some differences but cannot remove this limitation. Treatment adherence, additional care and loss to follow-up may also influence interpretation. The two participating centres may not represent all rehabilitation settings in Bangladesh.

The sample-size sensitivity calculation provides context for the recruitment target. Device settings, exercise dosage and session records describe the delivered programme beyond frequency and duration alone. Protocol amendments and deviations will be reported transparently. The completed trial should inform decisions about the added value and safety of the specified programme without implying that a positive result establishes the best SWD dose or justifies use in every low back pain population.

CONCLUSIONS

This protocol describes an assessor-blinded randomised comparison of active and sham SWD alongside the same conventional physiotherapy and home exercise advice in adults with clinically diagnosed discogenic low back pain. The primary analysis will estimate the additional effect of assignment to active SWD on pain at four weeks, with disability, later outcomes and adverse events providing further context. Interpretation will be limited to SWD as an adjunct to the shared rehabilitation programme. Clinical recommendations will depend on the magnitude, precision, durability and safety of the observed between-group effects.

DECLARATIONS

Ethics Approval Consent and Safety

Ethics approval details are provided in section 2.15. Written informed consent is required before study procedures, and consent documentation forms part of the study records. Participants may stop treatment or withdraw without affecting usual care. Safety, referral and injury-care arrangements follow the study procedures and institutional requirements. Instrument licence status is disclosed separately in section 2.10.

Protocol Access

Recruitment began on 1 June 2026 and ended on 27 July 2026. The full protocol and statistical analysis plan will be available from the corresponding author on reasonable request, subject to institutional requirements. Any public repository record established later will be cited in the trial report.

Consent for Publication

Not applicable to this protocol manuscript, which contains no identifiable participant information.

Data and Code Availability

No participant-level results are reported in this protocol. After study completion and publication, requests for de-identified trial data, the data dictionary and analysis syntax will be considered by the corresponding author. Release will depend on applicable consent, ethics and institutional authorisation and an appropriate confidentiality agreement. Direct identifiers will not be released. This statement does not imply that permission for unrestricted public data sharing has already been granted.

Competing Interests

The authors declare that they have no competing interests.

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Author Contributions

CRediT contributions and assigned trial responsibilities: Md. Akhter Hossain: Conceptualization, Methodology, Investigation, Resources, Data curation, Writing – original draft, Writing – review and editing, Project administration, and Funding acquisition

(personal funding). Planned analysis and reporting responsibilities include Software, Validation, Formal analysis and Visualization; these labels do not imply that final outcome analysis has already been completed. Md Ranzu Ahmed and Sarker Md Numan: Supervision. Recruitment of 208 participants has ended and follow-up is ongoing. Final analysis and reporting remain scheduled activities.

Use of Generative Artificial Intelligence

ChatGPT (OpenAI; GPT-6) was used to assist with manuscript drafting, restructuring and language editing. The authors are responsible for verifying the final text, references and consistency with the approved protocol before submission. Artificial intelligence was not used to generate participant data or trial results.

Preprint

This protocol has not been posted as a preprint.

Protocol Amendments Oversight and Dissemination

Material protocol changes require documentation by version and date and ethics review where applicable. Changes do not acquire retrospective approval from the date of this manuscript revision. The principal investigator coordinates conduct and authorised access to the final dataset; the statistician will lead the outcome analysis. Final reporting requires author review and approval. Findings will be disseminated irrespective of their direction, and a plain-language summary will be prepared for participants. Patient and public involvement is described in section 2.16.

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